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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of : Ling C. Santora et al.
Serial No. : 10/719,522
Filed : November 21, 2003
Entitled : METHOD FOR REDUCING OR
PREVENTING MODIFICATION
OF A POLYPEPTIDE IN
SOLUTION

ART UNIT: 1644

EXAMINER: Not yet assigned

Attorney Docket No. BBC-095

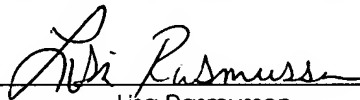
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

The undersigned hereby certifies that this correspondence is being deposited with the U.S. Postal Service as First Class Mail, in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

July 14, 2004

date of mailing and signature



Lisa Rasmussen

TRANSMITTAL LETTER

Sir/Madam:

Transmitted herewith are: [X] An Information Disclosure Statement under 37 CFR §§ 1.56, 1.97 and 1.98; [X] Form PTO-1449 Information Disclosure Statement; [X] A photocopy of each reference cited; and [X] An Acknowledgement Postcard; to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

[X] A fee for additional claims is not required.

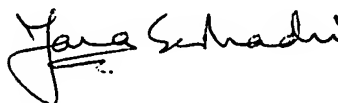
[] A fee for additional claims is required. The additional fee has been calculated as shown below:

	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	NUMBER OF EXCESS CLAIMS	RATE	FEES DUE
TOTAL CLAIMS			0	× \$18	= 0.00
INDEPENDENT			0	× \$84	= 0.00
FIRST INTRODUCTION OF MULT. DEPENDENT CLAIM				+\$280	= 0.00
TOTAL FEES DUE					= 00.00

PETITION FOR EXTENSION OF TIME

- ☐ Extension is requested under 37 CFR 1.136(a), and the following extension fee is applicable for the paper(s) filed herewith: ☐ \$110.00 for response within first month pursuant to 37 CFR 1.17(a)(1);
☐ \$420.00 for response within second month pursuant to 37 CFR 1.17(a)(2);
☐ \$950.00 for response within third month pursuant to 37 CFR 1.17(a)(3);
☐ \$1,480.00 for response within fourth month pursuant to 37 CFR 1.17(a)(4).
☐ \$2,010.00 for response within fifth month pursuant to 37 CFR 1.17(a)(5).
- ☒ The Commissioner is hereby authorized to charge payment of any additional fees required in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to **Deposit Account No. 010025**. A duplicate copy of this transmittal letter is transmitted herewith.

Respectfully submitted,



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July 14, 2004
Date

Lisa Rasmussen
Lisa Rasmussen

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §§ 1.56, 1.97 AND 1.98**

Sir/Madam:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicants submit this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 for the above-identified application. Applicants makes the following publications of record in the above-identified application.

US PATENT DOCUMENTS

Clark et al., 1995. US PAT. NO. 5,476,995.

Krimpenfort et al., 1992. US PAT. NO. 5,175,384

Meade et al., 1998. US PAT. NO. 5,827,690.

Page et al., 1996. US PAT. NO. 5,523,222.

US PATENT DOCUMENTS CONT.

Salfeld et al., 2000. US PAT. NO. 6,090,382.
Salfeld et al., 2001. US PAT. NO. 6,258,562 B1.
Velandar et al., 2002. US PAT. NO. 6,344,596.
Wagner et al., 1992. US PAT. NO. 5,175,385
Heine et al., 1990. US PAT. NO. 4,963,384

OTHER REFERENCES

Houdebine, 1994. J. Biotechnol. 34:269-287.
Boss et al., 1984. Nucleic Acids Res. 12:3791-3806.
Brem et al., 1993. Chim. Oggi . 11:21.
Campbell et al., 1996. Nature 380: 64-66.
Catinella et al., 1996a Rapid Commun. Mass Spectrom. 10:1123.
Catinella et al., 1996b Rapid Commun. Mass Spectrom. 10:1629.
Echelard, 1996 Curr. Opin. Biotechnol. 7:536-540.
Galvani et al., 2000. Rapid Commun. Mass Spectrom. 14:1889.
Hammer et al., 1985. Nature 315:680.
Houdebine, 1995. Reprod. Nutr. Dev. 35:609-617.
Houdebine, 2000. Transgenic Res. 9(4-5):305-320.
Jänne et al., 1992. Ann. Med . 24:273.
Jones et al., 1998. J. Chromtogr. A 822:147.
Jones et al., 1991. Bio/Technology 9:88.
McBurney et al., 1964. J. Lab. Clin. Med. 64:485.
Palmiter et al., 1985. Cell 41:343.
Pollock et al., 1999. J Immunological Meth. 231:147-157.
Sabbadin et al., 1999. Rapid Commun. Mass Spectrom. 13:1443.
Santora et al., 1999. Anal. Biochem. 275:98-108.
Siciliano et al., 2000. Anal. Chem. 72:408.
Fedele et al., 1999. J. Mass Spectrom. 34:1385.
Velandar et al., 1992. PNAS USA 89:12003.
Wilmut et al., 1997. Nature 385: 810-813.
Santora et al., 2001. Anal. Biochem. 299(2):119-229

Form PTO-1449 listing each of these documents and photocopies of each document are enclosed herewith for the Examiner's convenience.

This paper is being mailed before the mailing of a first office action on the merits in the above-identified application filed under 35 U.S.C §111 and 37 CFR §1.53(b). Pursuant to 37 CFR §1.97(b)(3), no fee is required with this submission.

Applicant does not intend to represent that any of the documents submitted herein is material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,



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INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

Docket Number (Optional)
BBC-095

Applicant(s)
Ling C. Santora et al.

Filing Date
November 21, 2003

Application Number
10/719,522

Group Art Unit
1644

INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		5,476,995	12/19/95	Clark et al.			
		5,175,384	12/29/92	Krimpenfort et al.			
		5,827,690	10/27/98	Meade et al.			
		5,523,222	06/04/96	Page et al.			
		6,090,382	07/18/00	Salfeld et al.			
		6,258,562	07/10/01	Salfeld et al.			
		6,344,596	02/05/02	Velander et al.			
		5,175,385	12/29/02	Wagner et al.			
		4,963,384	10/16/90	Heine et al.			

FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
	Houdebine, "Production of Pharmaceutical Proteins from Transgenic Animals", 1994. J. Biotechnol. 34:269-287.
	Boss et al., "Assembly of Functional Antibodies from Immunoglobulin Heavy and Light Chains Synthesised in E. Coli", 1984. Nucleic Acids Res. 12:3791-3806.

EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION

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Filing Date

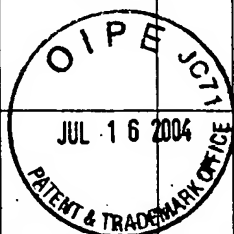
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Brem et al., "Comparative Analysis of Transgenic Expression in Mice", 1993. Chim. Oggi . 11:21.

Campbell et al., "Sheep Cloned by Nuclear Transfer from a Cultured Cell Line", 1996. Nature 380: 64-66.

Catinella et al., "Matrix-assisted Laser Desorption/Ionization Mass Spectrometry: a Valid Analytical Tool in the Dairy Industry", 1996a Rapid Commun. Mass Spectrom. 10:1123.

Catinella et al., "Matrix-assisted Laser Desorption/Ionization Mass Spectrometry in Milk", 1996b Rapid Commun. Mass Spectrom. 10:1629.

Echelard, "Recombinant Protein Production in Transgenic Animals", 1996 Curr. Opin. Biotechnol. 7:536-540.

Galvani et al., "Two-dimensional Gel Electrophoresis/Matrix-assisted laser Desorption/Ionisation Mass Spectrometry of Milk Powder", 2000. Rapid Commun. Mass Spectrom. 14:1889.

Hammer et al., "Production of Transgenic Rabbits, Sheep and Pigs by Microinjection", 1985. Nature 315:680.

Houdebine, "The Production of Pharmaceutical Proteins from the Milk of Transgenic Animals", 1995. Reprod. Nutr. Dev. 35:609-617.

Houdebine et al., "Transgenic Animal Bioreactors", 2000. Transgenic Res. 9(4-5):305-320.

Jänne et al., "Transgenic Animals as Bioproducers of Therapeutic Proteins", 1992. Ann. Med . 24:273.

Jones et al., "Analysis of the Maillard Reaction Products of β -lactoglobulin and Lactose in Skimmed Milk Powder by Capillary Electrophoresis and Electrospray Mass Spectrometry", 1998. J. Chromogr. A 822:147.


Jones et al., "Rapid PCR-Cloning of Full-Strength Mouse Immunoglobulin Variable Regions", 1991. Bio/Technology 9:88.

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		Filing Date November 21, 2003	Group Art Unit 1644

*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
	Wilmut et al., "Viable Offspring Derived From Fetal and Adult Mammalian Cells", 1997. Nature 385: 810-813.
	Yelander et al., "High-level Expression of a Heterologous Protein in the Milk of Transgenic Swine Using the cDNA Encoding Human Protein C", 1992. PNAS USA 89:12003.
	McBurney et al., "Device for Milking Mice", 1964. J. Lab. Clin. Med. 64:485.
	Palmiter et al., "Transgenic Mice", 1985. Cell 41:343.
	Pollock et al., "Transgenic Milk as a Method for the Production of Recombinant Antibodies", 1999. J Immunological Meth. 231:147-157.
	Sabbadin et al., "Matrix-assisted Laser Desorption/Ionization Mass Spectrometry in Evaluation of Protein Profiles of Infant Formulae", 1999. Rapid Commun. Mass Spectrom. 13:1443.
	Santora et al., "Characterization of Recombinant Human Monoclonal Tissue Necrosis Factor-alpha Antibody Using Cation-Exchange HPLC and Capillary Isoelectric Focusing", 1999. Anal. Biochem. 275:98-108.
	Siciliano et al., "Modern Mass Spectrometric Methodologies in Monitoring Milk Quality", 2000. Anal. Chem. 72:408.
	Fedele et al., "Qualitative Characterization of Bacterial Strains Employed in the Production of Yogurt by Matrix-assisted Laser Desorption/Ionization Mass Spectrometry", 1999. J. Mass Spectrom. 34:1385.
	Santora et al., "Characterization of Noncovalent Complexes of Recombinant Human Monoclonal Antibody and Antigen Using Cation Exchange, Size Exclusion Chromatography, and BIAcore", 2001. Anal. Biochem. 299(2):119-229

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